(24)

FILED
FEB 6 - 2006
OFFICE OF THE CLERK
SUPREME COURT, U.S.

No. 04-607

IN THE

Supreme Court of the United States

LABORATORY CORPORATION OF AMERICA HOLDINGS, D/B/A LABCORP,

Petitioner,

v.

METABOLITE LABORATORIES, INC. AND COMPETITIVE TECHNOLOGIES, INC.,

Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF *AMICUS CURIAE* FRANKLIN PIERCE LAW CENTER IN SUPPORT OF THE RESPONDENTS

CRAIG STEVEN JEPSON
Professor of Law
Counsel of Record

FRANKLIN PIERCE
LAW CENTER
2 White Street
Concord, NH 03301
(603) 228-1541

Amicus Curiae

WILSON-EPES PRINTING CO., INC. – (202) 789-0096 – WASHINGTON, D. C. 20001

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES iii

INTEREST OF *AMICUS CURIAE* 1

DISCUSSION 2

SUMMARY OF ARGUMENT 3

ARGUMENT 4

I. THIS COURT HAS NEVER INVALIDATED A PATENT CLAIM FOR CLAIMING A LAW OF NATURE. 6

A. Birth of the Prohibition: The First Patent Claims to Laws of Nature Were Upheld.. 6

B. Many Decisions Purporting to Invalidate Patent Claims to Laws of Nature Do So Only by Importing Conditions of Patentability from Statutory Provisions.. 9

II. SOUND POLICY SUPPORTS ISSUANCE OF CLAIMS DIRECTED TO LAWS OF NATURE. 12

A. Reinvigorating Our Patent System Reinvigorated Our Economy..... 13

B. Expanding the Scope of Subject Matter Protectable by Patent-like Incentives Fosters Innovation. 17

III. THIS CASE IS THE APPROPRIATE VEHICLE FOR BUILDING ON *CHAKRABARTY* AND *DIEHR*. 21

A. The Prohibition is Arbitrary and Has Always Been Difficult to Apply. 22

B. This Court and Congress Consistently Have Moved Away from Arbitrary Line Drawing Regarding Patentable Subject Matter. 27

CONCLUSION 30

TABLE OF AUTHORITIES

Cases	Page
Am. Fruit Growers, Inc. v. *Brogdex Co.*, 283 U.S. 1 (1931)	27
Brenner v. *Manson*, 383 U.S. 519 (1966)	14
Cohens v. *Va.*, 19 U.S. (6 Wheat.) 264 (1821)	8
Dawson Chem. Co. v. *Rohm & Haas Co.*, 448 U.S. 176 (1980)	16, 17
De Forest Radio Co. v. *Gen. Elec. Co.*, 283 U.S. 664 (1931)	7
Diamond v. *Chakrabarty*, 447 U.S. 303 (1980)	4, 6, 16, 27
Diamond v. *Diehr*, 450 U.S. 175 (1981)	passim
Dolbear v. *Bell*, 126 U.S. 1 (1888)	22
Eibel Process Co. v. *Minn. & Ont. Paper Co.*, 261 U.S. 45 (1923)	11
Funk Bros. Seed Co. v. *Kalo Inoculant Co.*, 333 U.S. 127 (1948)	6, 10, 27
Gottschalk v. *Benson*, 409 U.S. 63 (1972)	6, 27
Graham v. *John Deere Co.*, 383 U.S. 1 (1966)	14
Household Coal & Iron Co. v. *Neilson*, 1 Webs. Pat. Cas. 673 (S.C.(H.L.) 1843)	8

Cases—Cont'd **Page**

In re Breslow,
616 F.2d 516 (C.C.P.A. 1980) 21

In re Gulack,
703 F.2d 1381 (Fed. Cir. 1983) 28

In re Miller,
418 F.2d 1392 (C.C.P.A. 1969) 28

In re Schrader,
22 F.3d 290 (Fed. Cir. 1994) 29

In re Tarczy-Hornoch,
397 F.2d 856 (C.C.P.A. 1968) 28

In re Walter,
618 F.2d 758 (C.C.P.A. 1980) 11

Jungerson v. *Ostby & Barton Co.*,
335 U.S. 560 (1949) 13

Katz v. *Horni Signal Mfg. Corp.*,
145 F.2d 961 (2d Cir. 1944) 11

Le Roy v. *Tatham*,
55 U.S. (14 How.) 156 (1853) 6, 7, 22

Le Roy v. *Tatham*,
63 U.S. (22 How.) 132 (1860) 8

Neilson v. *Harford*,
151 Eng. Rep. 1266 (Exch. 1841) 8

O'Reilly v. *Morse*,
56 U.S. (15 How.) 62 (1853) ..... passim

Parker v. *Flook*,
437 U.S. 584 (1978) 6, 9, 14

Pres. & Fellows of Harvard Coll. v. *Can. (Comm'r of Patents)*,
[2000] 4 F.C. 528 26

Cases—Cont'd **Page**

Reiner v. *I. Leon Co.*,
285 F.2d 501 (2d Cir. 1960) 13

Republic Indus., Inc. v. *Schlage Lock Co.*,
592 F.2d 963 (7th Cir. 1979) 14

Risdon Iron & Locomotive Works v. *Medart*,
158 U.S. 68 (1895) 28

Sakraida v. *Ag Pro, Inc.*,
425 U.S. 273 (1976) 14

Smith v. *Downing*,
22 F. Cas. 511 (C.C.D. Mass. 1850) 23

SmithKline Beecham Corp. v. *Apotex Corp.*,
403 F.3d 1331 (Fed. Cir. 2005) 26

State St. Bank & Trust Co. v. *Signature Fin. Group, Inc.*, 149 F.3d 1368 (Fed. Cir. 1998) 5, 10, 29

Tilghman v. *Proctor*,
102 U.S. 707 (1881) 22, 24, 25, 26

Statutes

21 U.S.C. § 355a (2000) 20

35 U.S.C. § 101 (2000) 2

35 U.S.C. § 102 (2000) 2

35 U.S.C. § 103 (2000) 2

35 U.S.C. § 112 (2000) 2

35 U.S.C. § 154 (2000) 3

Legislative Materials **Page**

American Patent System: Hearings on S. Res. 92 Before the Subcomm. On Patents, Trademarks, & Copyrights of the Comm. on the Judiciary, 84th Cong. (1955) ... 12

Bayh-Dole Act of 1980,
Pub. L. No. 96-517, 94 Stat. 3015 (1980) 15

Econ. Recovery Tax Act of 1981,
Pub. L. No. 97-34, 95 Stat. 172 (1981) 15

Fed. Courts Improvement Act of 1982,
Pub. L. No. 97-164, 96 Stat. 25 (1982) 15

Fed. Tech. Transfer Act of 1986,
Pub. L. No. 99-502, 100 Stat. 1785 (1986) 15

Food & Drug Admin. Modernization Act of 1997,
Pub. L. No. 105-115, 111 Stat. 2296 (1997) 20

H.R. Rep. No. 82-1923 (1952) 4

Orphan Drug Act of 1983,
Pub. L. No. 97-414, 96 Stat. 2049 (1983) 18

Patent Law Amendments Act of 1984,
Pub. L. No. 98-622, 98 Stat. 3383 (1984) 15, 16

Patent Law Codification & Revision: Hearings on H.R. 3760 Before Subcomm. No. 3 of the House Comm. on the Judiciary, 82d Cong. (1951)..... 4

Patent Misuse Reform Act of 1988,
Pub. L. No. 100-703, 102 Stat. 4674 (1988) 16

Process Patent Amendments Act of 1988,
Pub. L. No. 100-418, 102 Stat. 1107 (1988) 16

S. Rep. No. 82-1979 (1952)..... 4

Stevenson-Wydler Technology Innovation Act of 1980,
Pub. L. No. 96-480, 94 Stat. 2311 (1980) 15

Legislative Materials—Cont'd **Page**

The Pediatric Exclusivity Provision: U.S. Food & Drug Admin. Jan. 2001 Status Report to Congress (2001) 20

Other Materials

Anand, B. & T. Khanna,
The Structure of Licensing Contracts,
48 J. Indus. Econ. 103 (2000) 15

Arora, A., et al.,
Markets for Technology: Economics of Innovation and Corporate Strategy (MIT Press 2001)..... 14

Beyond Borders: Global Biotechnology Report 2005
(Ernst & Young 2005) 19

Beyond Borders: The Global Biotechnology Report 2002
(Ernst & Young 2002) 18

Biological Sciences,
14 Encyclopedia Britannica 1069 (15th ed. 2005).... 23

Carr, Geoffrey,
A Survey of the Pharmaceutical Industry: The Alchemists, Economist, Feb. 21, 1998 17

Chevreul, M. E.,
De la Loi du Contraste Simultané des Couleurs et de l'assortiment des Object Colorés (Paris 1839)..... 25

Chisum, Donald S.,
Chisum on Patents (2005)..... 14, 16

Duffy, John F.,
The Festo Decision and the Return of the Supreme Court to the Bar of Patents,
2002 Sup. Ct. Rev. 273 (2002) 13

Electricity and Magnetism,
18 Encyclopedia Britannica 159 (15th ed. 2005)..... 23

Other Materials—Cont'd **Page**

Geriak, James W.,
Synergism—How Long Will the Malady Linger On?
1980 Pat. L. Ann. 51 (1980) 14

Lichtenberg, Frank R. & Joel Waldfogel,
Does Misery Love Company? Evidence from pharmaceutical markets before and after the Orphan Drug Act,
NBER Working Paper No. 9750 (June 2003) 18

Manual of Patent Examining Procedure
(8th ed., Rev. Aug. 2005) 21

Milne, Christopher-Paul
Exploring the Frontiers of Law and Science: FDAMA's Pediatric Studies Incentive,
57 Food & Drug L.J. 491 (2002) 19

Nat'l Research Council of the Nat'l Acads.,
A Patent System for the 21st Century (Stephen A. Merrill, et al., eds. 2004) 14, 15, 17

Note, *FDA Reform and the European Medicines Evaluation Agency,*
108 Harv. L. Rev. 2009 (1995) 18

Park, W. & J. Ginarte,
Intellectual Property Rights and Economic Growth,
15 Contemp. Econ. Pol'y 51 (1997) 16

Shapiro, Gilbert,
A Skeleton in the Darkroom: Stories of Serendipity in Science (HarperCollins 1986) 23

Story, J.,
On the Patent Laws,
16 U.S. (3 Wheat.) app. n. (ii) (1818) 11

Other Materials—Cont'd **Page**

U.S. Food & Drug Admin. Ctr. for Drug Evaluation & Research, *Pediatric Drug Development*, http://www.fda.gov/cder/pediatric/ (last visited Jan. 31, 2006) 21

U.S. Food & Drug Admin., *List of Orphan Designations & Approvals*, http://www.fda.gov/orphan/designat/list.htm (last visited Jan. 31, 2006) 18

U.S. Pat. No. 11,766 25

U.S. Pat. No. 4,736,866 26

Webster, Daniel, 12 Encyclopedia Britannica 549 (15th ed. 2005) 6

IN THE

Supreme Court of the United States

No. 04-607

LABORATORY CORPORATION OF AMERICA HOLDINGS, D/B/A LABCORP,

Petitioner,

v.

METABOLITE LABORATORIES, INC. AND COMPETITIVE TECHNOLOGIES, INC.,

Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF *AMICUS CURIAE* FRANKLIN PIERCE LAW CENTER IN SUPPORT OF THE RESPONDENTS

INTEREST OF *AMICUS CURIAE* [1]

Amicus curiae Franklin Pierce Law Center (hereafter "Pierce Law") is an accredited law school located in Concord, New Hampshire. From its

[1] Both parties have consented to the filing of this brief *amicus curiae*. The letters of consent have been filed with the Clerk of the Court. This brief was not authored, in whole or in part, by counsel to a party, and no monetary contribution to the preparation or submission of this brief was made by any person or entity other than the *amicus curiae*. *Amicus Curiae* gratefully acknowledges the assistance of law students C. Gideon Korrell and Sean Tassi.

founding in 1973, a principal mission of Pierce Law has been the teaching of patent law and practice. The sole interest of *Amicus Curiae* in this case is the proper development and application of patent law to promote innovation and economic progress.

DISCUSSION

A number of provisions in the Patent Laws limit the scope of an inventor's patent rights. The invention must be patentable subject matter, i.e. "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." 35 U.S.C. § 101 (2000); *see also Diamond* v. *Diehr*, 450 U.S. 175, 182 (1981) ("Congress intended statutory subject matter to 'include anything under the sun that is made by man.'") (expanding patentable processes to include computer-program related inventions). The invention must have demonstrable utility; the invention must be novel and nonobvious. 35 U.S.C. §§ 101-103 (2000).

In addition, the inventor must comply with certain formal requirements. The specification must include a written description of the invention sufficient to enable a person having ordinary skill in the art (hereafter "POSA") to which the patent is most closely related to make and use the invention. In addition, the inventor must disclose her best mode of practicing the invention, and must distinctly claim the subject matter of her invention. 35 U.S.C. § 112, ¶¶ 1, 2 (2000). Only after meeting these requirements does an inventor qualify for her

patent rights, and then only for a limited time. 35 U.S.C. § 154(a)(2) (2000).

While the question this Court presented for review does not facially challenge the standards for patentable subject matter, the invitation of this Court to the Solicitor General indicates an interest in considering whether the patent-in-suit claims patentable subject matter. The Solicitor General counseled denial of the petition for writ of certiorari and endorsed as correct the application by the PTO of this Court's standards articulated in *Diehr*.

Pierce Law agrees that the PTO correctly applied the standards for patentable subject matter set forth in *Diehr*. Pierce Law urges, however, that this case is the appropriate vehicle for building upon *Diehr* by discarding the judicially-created prohibition against patent claims directed to so-called laws of nature.

SUMMARY OF ARGUMENT

This Court should discard the prohibition against patent claims directed to so-called laws of nature. The prohibition arose from dicta contained in old, English, common law decisions. It has no statutory support in our law. It is unnecessary and nearly impossible to apply because it is error-prone, redundant, and obsolete.

This Court has never invalidated a patent claim for claiming a law of nature. This Court has, instead, correctly relied only on statutory authority mandated by Congress in 1952 under 35 U.S.C. §§ 102, 103, and 112.

Recent experience in the United States shows that when this Court, the Legislature, or the Executive has rejuvenated a component of our patent system, that action has rejuvenated a component of our economy.

The prohibition against claims directed to laws of nature is a relic, an arbitrary bar to patentability, such as Congress and this Court consistently have acted to eliminate.

ARGUMENT

Congress never intended patentability to turn on whether what is claimed might be considered a law of nature. Congress intended patentability to turn only on whether what is claimed, when viewed as a whole, meets the requirements of patentability as set forth in 35 U.S.C. §§ 101, 102, and 103.[2] The Committee Reports accompanying the 1952 Patent Act reveal that Congress intended statutory subject matter to "include anything under the sun that is made by man."[3] S. Rep. No. 82-1979, at 5 (1952); H.R. Rep. No. 82-1923, at 6 (1952). *See also* *Diamond* v. *Chakrabarty*, 447 U.S. 303, 315 (1980)

---

[2] "The repetitive use of the expansive term 'any' in § 101 shows Congress's intent not to place any restrictions on the subject matter for which a patent may be obtained beyond those specifically recited in § 101." *State St. Bank & Trust Co.* v. *Signature Fin. Group, Inc.*, 149 F.3d 1368, 1373 (Fed. Cir. 1998) (Rich, J.).

[3] P. J. Frederico, a principal draftsman of the 1952 Patent Act, also employed this expansive language in his testimony regarding that legislation: "[U]nder section 101 a person may have invented a machine or a manufacture, which may include anything under the sun that is made by man * * *." *Patent Law Codification & Revision: Hearings on H.R. 3760 Before Subcomm. No. 3 of the House Comm. on the Judiciary*, 82d Cong. 37 (1951).

("Congress, not the courts, must define the limits of patentability"); *State St. Bank & Trust Co.*, 149 F.3d at 1374-75 (Rich, J.) (explaining that under the 1952 Patent Act, many once-held exclusions are no longer applicable).

This mandate reflects the role of the Constitution in protecting the rights of Citizens:

> The law acknowledges the existence of the right of an inventor to his invention as property, and the Constitution is remarkably exact in the language in which it speaks of this important subject. The Constitution does not attempt to give an inventor a right to his invention * * *. No such thing. But the Constitution *recognizes* an original, pre-existing, inherent right of property in the invention, and authorizes Congress to secure to inventors the enjoyment of that right. But the right existed before the Constitution and above the Constitution, and is, as a natural right, more clear than that which a man can assert in almost any other kind of property. * * * Invention, as a right of property, stands higher than inheritance or devise, because *it is personal earning*.

Argument by Daniel Webster for Charles Goodyear in the patent case *Charles Goodyear* v. *Horace H. Day*, United States Circuit Court for the District of New Jersey, March, 1852. (emphasis in original).[4]

---

[4] Daniel Webster was born in Salisbury, N.H., January 18, 1782, attended Phillips Exeter Academy, Exeter, N.H., and in 1801 graduated from Dartmouth College, Hanover, N.H. The citizens of New Hampshire elected him as a Federalist to the Thirteenth and

I. THIS COURT HAS NEVER INVALIDATED A PATENT CLAIM FOR CLAIMING A LAW OF NATURE.

Because this Court has never invalidated a patent claim for being directed to a so-called law of nature, this Court should affirmatively discard the prohibition. Absent such direction, the lower courts will fail to embrace the broadest scope for patentable subject matter, as was mandated by Congress. Instead, courts will mistakenly continue to follow obiter dicta imported from English common law. That dicta has given rise to a false notion: That so-called laws of nature are unpatentable.

A. Birth of the Prohibition: The First Patent Claims to Laws of Nature Were Upheld.

This Court dates the prohibition against claiming laws of nature to *Le Roy* v. *Tatham* (*Le Roy I*), 55 U.S. (14 How.) 156 (1853). *See Diehr*, 450 U.S. at 185 (relying on *Le Roy*); *Chakrabarty*, 447 U.S. at 309 (relying on *Le Roy*); *Parker* v. *Flook*, 437 U.S. 584, 588-89 (1978) (relying on *Le Roy*); *Gottschalk* v. *Benson*, 409 U.S. 63, 67 (1972) (relying on *Le Roy*); *Funk Bros. Seed Co.* v. *Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948) (relying on *Le Roy*); *De Forest Radio Co.* v. *Gen. Elec. Co.*, 283 U.S. 664, 685 (1931) (relying on *Le Roy* for the

---

Fourteenth Congresses (March 4, 1813-March 3, 1817). He represented Dartmouth College before this Court in *The Dartmouth College Case*, 17 U.S. (4 Wheat.) 518 (1819). *Webster, Daniel*, 12 Encyclopedia Britannica 549 (15th ed. 2005).

notion that scientific methods, not explanations, are patentable); *O'Reilly* v. *Morse*, 56 U.S. (15 How.) 62, 114-18 (1853) (citing *Le Roy* and English common law).

Tatham was the assignee of the Hanson patent for an improved method of manufacturing by extruding pipes from soft metals such as lead. *Le Roy I*, 55 U.S. at 172. The Hanson patent embodied the mechanics of an earlier invention patented in 1820. Hanson's invention, however, used a newly-discovered property in metals (that they may be recombined and strengthened when placed under extreme pressure) which resulted in a marked improvement in pipe manufacturing—wrought pipe rather than cast pipe. *Id.* at 174. This Court wrote that while natural "processes used to extract, modify, and concentrate natural agencies" are inventive, the patentable "invention is not in discovering them, but in applying them to useful objects." *Id.* at 175 ("A new property discovered in matter, when practically applied, in the construction of a useful article of commerce or manufacture, is patentable").

That discussion, however, was obiter dictum, as this Court wrote: "The question whether the newly developed property of lead * * * might have been patented, if claimed as developed * * * was not in the case." *Id.* at 177. Indeed, this Court ultimately upheld Hanson's patent while acknowledging that it was on a law of nature:

> 'A patent will be good, though the subject of the patent consists in the discovery of a great,

> general and most comprehensive principle in science or law of nature, if that principle is, by the specification, applied to any special purpose, so as thereby to effectuate a practical result and benefit not previously attained.'

Le Roy v. *Tatham* (*Le Roy II*), 63 U.S. (22 How.) 132, 135-36 (1860) (quoting *Household Coal & Iron Co.* v. *Neilson*, 1 Webs. Pat. Cas. 673, 683 (S.C.(H.L.) 1843) (also upholding a patent directed to a law of nature)).

In *Neilson*, James Beaumont Neilson's invention was the pre-heating of air before sending it into a blast furnace. Use of the invention increased the temperature of the fire in the blast furnace and the efficiency of iron smelting. *Neilson* v. *Harford*, 151 Eng. Rep. 1266 [1 Webs. Pat. Cas. 328] (Exch. 1841). No device was claimed, which raised the question of whether Neilson claimed a mere principle or instead a patentable process. The English court upheld the patent as directed to a patentable process. *Id.* at 1274. Thus, the foundation for the judicially created prohibition against patent claims directed to so-called laws of nature is at best obiter dictum.

A dictum that has not acquired a gloss in reason should not be followed. In *Cohens* v. *Va.*, 19 U.S. (6 Wheat.) 264 (1821), Chief Justice Marshall disapproved reliance on dicta:

> It is a maxim not to be disregarded, that general expressions, in every opinion, are to be taken in connection with the case in which those expressions are used. If they go beyond the

> case, they may be respected, but ought not to control the judgment in a subsequent suit when the very point is presented for decision. The reason of this maxim is obvious. The question actually before the Court is investigated with care and considered in its full extent. Other principles which may serve to illustrate it, are considered in their relation to the case decided, but their possible bearing on all other cases is seldom completely investigated.

Id. at 399-400.

Because the dictum from *Le Roy* "ought not to [have controlled] the judgment in [the] subsequent" cases, those cases on this point are entitled to little weight.

B. Many Decisions Purporting to Invalidate Patent Claims to Laws of Nature Do So Only by Importing Conditions of Patentability from Statutory Provisions.

Many decisions seen as turning on unpatentable subject matter have, on closer reading, turned on statutory criteria imported from 35 U.S.C. §§ 102, 103, or 112. *See Flook*, 437 U.S. at 600 (Stewart, J., dissenting). In these decisions, reliance on one or more of §§ 102, 103, or 112 to invalidate the patent claims would have been appropriate, but the reliance on unpatentable subject matter was misplaced.

An example is *Funk Bros. Seed Co.*, 333 U.S. at 127 (denying patentability as "natural

phenomenon" to man-made mixture of six isolated bacterium recombined in respective quantities so as to be noninhibitive of each other), which actually was decided on the basis of what would soon thereafter become known as 35 U.S.C. § 103 obviousness:

> There is, of course, an advantage in the combination. The farmer need not buy six different packages for six different crops. He can buy one package and use it for any or all of his crops of leguminous plants. And, as respondent says, the packages of mixed inoculants also hold advantages for the dealers and manufacturers * * * . But a product must be more than new and useful to be patented; it must also satisfy the requirements of invention or discovery.

Id. at 131.

Likewise, Judge Rich explicated in *State St. Bank & Trust Co.*, 149 F.3d at 1376, that all the decisions that had been thought to hold that business methods were not patentable subject matter were, on closer reading, based on statutory grounds (35 U.S.C. § 102 (novelty) or § 103 (obviousness)). The courts had blurred the subject matter requirement with those statutory requirements.

The blurring is understandable because in one sense, the prohibition against patent claims directed to so-called laws of nature is but an undeniable truism: At some level of abstraction the statutory requirements for patentability cannot be

met. *See In re Walter*, 618 F.2d 758, 769 (C.C.P.A. 1980) (Rich, J.) ("One could as easily say that the inclined paper-making wire in *Eibel Process Co.* [v. *Minn. & Ont. Paper Co.*, 261 U.S. 45 (1923)] was on a fundamental level, mathematical in nature because it operated according to the law of gravity * * * ."); *Katz* v. *Horni Signal Mfg. Corp.*, 145 F.2d 961, 961 (2d Cir. 1944) (J. Frank, J., A. Hand, & T. Swan, JJ.) ("Epoch-making 'discoveries' of 'mere' general scientific 'laws,' without more, cannot be patented."). Justice Story explained:

> A patent cannot be for a mere principle, properly so called; that is, for an elementary truth. But the word principle is often used in a more lax sense, to signify constituent parts, peculiar structure, or process; and in specifications, it is generally used in this latter sense; and in this view, it may well be the subject of a patent.

J. Story, *On the Patent Laws*, 16 U.S. (3 Wheat.) app. n. (ii) at 15-16 (1818). Thus, where courts have not clearly seen that claims should be rejected as not being novel and nonobvious, courts have resorted, mistakenly, to subject matter.

Therefore, the prohibition against claims directed to so-called laws of nature—in addition to being judicially created and founded in dicta—is unnecessary. The prohibition is also unworkable and contrary to sound economic policy.

II. SOUND POLICY SUPPORTS ISSUANCE OF CLAIMS DIRECTED TO LAWS OF NATURE.

We have learned much since 1955 when Judge Learned Hand testified on the American Patent System:

> You can find—I have been at the job nearly 50 years—there are two schools and the one school beats the air and says without the patent system the whole of American industry would never have developed. It is the stimulus which has brought us to the top, and the other says it is nothing but a beastly method * * * .
>
> No one really knows. Each side is beating the air.

American Patent System: Hearings on S. Res. 92 Before the Subcomm. On Patents, Trademarks, & Copyrights of the Comm. on the Judiciary, 84th Cong. 116 (1955).

We are beating the air no longer. Recent changes in laws related to patents prove that expanding the scope of subject matter protected by patents, rather than contracting it, fosters growth and innovation.

A. Reinvigorating Our Patent System Reinvigorated Our Economy.

The United States patent system was robust until the early part of the last century when the judiciary slowly soured on it:[5]

> There can be no doubt that the Act of 1952 [was] meant to change [that] slow but steady drift of judicial decision that had been hostile to patents which made it possible for Mr. Justice Jackson in dissent to speak of the 'strong passion in this Court for striking them' (patents) 'down so that the only patent that is valid is one which this Court has not been able to get its hands on.'

Reiner v. *I. Leon Co.*, 285 F.2d 501, 503 (2d Cir. 1960) (L. Hand, J.) (quoting *Jungerson* v. *Ostby & Barton Co.*, 335 U.S. 560, 572 (1949)). Unfortunately, the anti-patent hostility of the courts continued.[6]

---

[5] "The importance of federal patent law during the nineteenth century can be measured not only in terms of the lawyers attracted to the field, but also in the treatment that the subject received at the Court." John F. Duffy, *The Festo Decision and the Return of the Supreme Court to the Bar of Patents*, 2002 Sup. Ct. Rev. 273, 274-75 (2002). In upholding Alexander Graham Bell's patents in the *Telephone Cases*, this Court consolidated five matters, heard oral argument over twelve days, and filed a report filling an entire volume of the U.S. Reports. *Id.* at 275. Particularly interested in patent law, Justice Story wrote a number of seminal opinions and articles that are still referred to today. *Id.* "And, even when the Court was drowning in appeals toward the end of the century, retiring Justice William Strong supported a congressional proposal that would have limited the Court's mandatory appellate jurisdiction except in patent and copyright cases." *Id.*

[6] *See* James W. Geriak, *Synergism—How Long Will the Malady Linger On?* 1980 Pat. L. Ann. 51 (1980) (discussing various

As our patent system weakened, our economy weakened. "[In] the 1970s, when productivity growth rates fell sharply" and in the 1980s, "when Japanese competition fostered the notion that U.S. manufacturing industries were on the decline," the bar, industry, and government mobilized. Nat'l Research Council of the Nat'l Acads., *A Patent System for the 21st Century* at 18 (Stephen A. Merrill, et al., eds. 2004). Consequently, "[t]he 1980s saw [an] upward surge in the role and importance of the patent system." 1 Donald S. Chisum, *Chisum on Patents* § 7 (2005). "Beginning in 1980 a series of legislative actions, judicial decisions, executive branch initiatives, and international agreements * * * strengthened the rights of intellectual property owners [by extending rights] into new areas of technology." *A Patent System for the 21st Century* at 21-22.[7]

---

reincarnations of tests for patentability which have "clouded the minds of the courts"); *see also Flook*, 437 U.S. at 584 (1978) (claimed process lost status as patentable subject matter simply because one step in the process would not be patentable subject matter if considered in isolation.); *Sakraida* v. *Ag Pro, Inc.*, 425 U.S. 273 (1976) (disparaging patents to so-called "co· ıbinations"); *Brenner* v. *Manson*, 383 U.S. 519 (1966) (inventor must disclose in application a specific practical utility); *Republic Indus., Inc.* v. *Schlage Lock Co.*, 592 F.2d 963, 964-65 (7th Cir. 1979) ("Increasingly, the district courts in this circuit * * * have taken the view that synergism and not the criteria articulated in *Graham* v. *John Deere Co.*, 383 U.S. 1 (1966), is the controlling test in combination patent claims.").

[7] "The 'pro-patent' era is unquestionably associated with a rapid growth in the markets for new knowledge. On the basis of secondary data, Arora and colleagues [Arora, A., A. Fosfuri, and A. Gambardella, *Markets for Technology: Economics of Innovation and Corporate Strategy* (MIT Press 2001)] roughly estimate that the value of technology licensing in the United States increased from $24 billion in 1990 to $44 billion in 1995 in constant dollars, and the

Congress began the movement by enacting important, pro-patent legislation.[8] In 1982, Congress created the United States Court of Appeals for the Federal Circuit and gave it exclusive appellate jurisdiction over cases that arise under the patent laws. Federal Courts Improvement Act of 1982, Pub. L. No. 97-164, 96 Stat. 25 (codified as amended 28 U.S.C. § 1295(a)(1) (1995)). In 1984, Congress passed the Patent Law Amendments Act amending 35 U.S.C. §§ 103, 116, and 120, which changed the "complex body of case law [that discouraged] communication among members of research teams working in corporations, universities or other organizations." Patent Law Amendments Act of 1984, Pub. No. L. 98-622, § 104, 98 Stat. 3383 (codified as amended in scattered sections of 35 U.S.C. (1988)). Congress also amended the infringement statute at 35 U.S.C. § 271(f) to make an infringing act the exportation of

---

number of deals increased from more than 200 to well over 2,100." *Id.* at 37. In addition, "Anand and Khanna [Anand, B. & T. Khanna, *The Structure of Licensing Contracts*, 48 J. Indus. Econ. 103, 135 (2000)] support the hypothesis of a direct relationship by showing that licensing is more frequent in industries where patents are also prevalent." *Id.*

[8] Important legislation facilitated moving university research to production lines and encouraged the commercial exploitation of federally funded research. *See* Fed. Tech. Transfer Act of 1986, Pub. L. No. 99-502, 100 Stat. 1785 (1986) (codified as amended at 15 U.S.C. § 3701 et seq. (1988)); Econ. Recovery Tax Act of 1981, Pub. L. No. 97-34, 95 Stat. 172, 241 (1981) (codified as amended at scattered sections of 26 U.S.C. (1984)); Bayh-Dole Act, Pub. L. No. 96-517, 94 Stat. 3015, 3019-28 (1980) (codified as amended at 35 U.S.C. §§ 200-212 (1984)); Stevenson-Wydler Technology Innovation Act of 1980, Pub. L. No. 96-480, 94 Stat. 2311 (1980) (codified as amended at 15 U.S.C. § 3701 et seq. (1984)).

components of a patented combination. Patent Law Amendments Act of 1984, Pub. L. No. 98-622, 98 Stat. 3383 (codified as amended in scattered sections of 35 U.S.C. (1988)). In 1988, Congress passed the Patent Misuse Reform Act, Pub. L. No. 100-703, 102 Stat. 4674, 4676 (codified as amended at 35 U.S.C. § 271(d) (1994)), restricting application of the misuse doctrine to certain patent licensing and sales practices. The same year, it enacted the Process Patent Amendments Act, Pub. L. No. 100-418, 102 Stat. 1107, 1563 (codified as amended at 35 U.S.C. § 271(g) (1994)), extending to owners of patents with claims directed to processes the right to exclude unauthorized importation of unpatented products made abroad by use of the claimed processes. 1 *Chisum on Patents* § 7 (enumerating important legislation that reinvigorated the economy).[9]

This Court followed Congress's lead, also expanding the subject matter protectable by patents. *Chakrabarty*, 447 U.S. at 318, upheld the patentability of genetically-altered living microorganisms. *Dawson Chem. Co.* v. *Rohm & Haas Co.*, 448 U.S. 176, 201 (1980), applied 35 U.S.C. § 271(d) to hold that the owner of a patent claiming a process of using an unpatented (and

---

[9] Empirical research from 60 countries for the period 1960-1990 shows that the strength of patent protection is positively and significantly correlated with investment in research and development in modern economies. *See* Park, W. & J. Ginarte, *Intellectual Property Rights and Economic Growth*, 15 Contemp. Econ. Pol'y 51 (1997) (indexing the strength of patent protection in 60 countries to determine the role of intellectual property rights in economic growth).

unpatentable) herbicide had not misused the patent when he sold the herbicide but refused to license the process to competing manufacturers of the herbicide. This Court held that because the herbicide was not a staple suited for uses other than in the patented process, the patent owner was not unlawfully extending the scope of the patent claims. *Id.* at 201, 214 ("the provisions of § 271(d) effectively confer upon the patentee, as a lawful adjunct of his patent rights, a limited power to exclude others from competition in nonstaple goods."). Thus, this Court extended the subject matter protectable by patents.

Reinvigorating the patent system worked. "[By] the mid-1990s the [United States] economy was again exhibiting high productivity growth." *A Patent System for the 21st Century* at 18.

B. Expanding the Scope of Subject Matter Protectable by Patent-like Incentives Fosters Innovation.

By the early 1980s, twenty-five million Americans suffered from one or more of six thousand diseases so rare that they presented little economic incentive to drug innovators.[10] Therefore, to "provide [patent-like] incentives for drug companies to develop and manufacture products for rare diseases that would otherwise produce

---

[10] Drug companies will not decide, *ex ante*, to risk capital on drug development unless there is a reasonable prospect of a substantial return. *See* Geoffrey Carr, *A Survey of the Pharmaceutical Industry: The Alchemists*, Economist, Feb. 21, 1998, at 4 of insert (reporting estimate of 13 years and 300 million dollars to develop a new drug).

insufficient patient demand to support drug development, Congress in 1983 enacted the Orphan Drug Act. See 21 U.S.C. 360aa-ee (1988)." Note, *FDA Reform and the European Medicines Evaluation Agency*, 108 Harv. L. Rev. 2009, 2013 n.24 (1995).[11] These patent-like incentives, which expanded the subject matter eligible for protection, fostered drug development.

In the ten years prior to enactment of the Orphan Drug Act ("ODA"), the FDA reports, only ten products for rare diseases were developed and approved for marketing without federal funding.[12] Since the passage of the ODA, however, the FDA has approved for market 283 orphan drugs and biologics. U.S. Food & Drug Admin., *List of Orphan Designations & Approvals*, http://www.fda.gov/orphan/designat/list.htm (last visited Jan. 31, 2006). The FDA also reports that more than 1,544 orphan designated products are in development. *Id.* Our enlightened expansion of the scope of protectable subject matter blazed a path for the rest of the developed world. *See Beyond Borders: The Global Biotechnology Report 2002*, at 107 (Ernst & Young 2002) ("Since introduction of

---

[11] These provisions "allow tax credits for money spent on clinical testing of drugs for a 'rare disease or condition,' defined as one that affects fewer than 200,000 persons," as well as "drugs that are expected to cost more than they will earn on the market." *Id.* In addition, "the Act provides manufacturers with seven years of post-approval market exclusivity for any unpatentable orphan drug." *Id.*

[12] Frank R. Lichtenberg & Joel Waldfogel, *Does Misery Love Company? Evidence from pharmaceutical markets before and after the Orphan Drug Act*, NBER Working Paper No. 9750 (June 2003) *available at* http://papers.nber.org/papers/w9750.

the orphan drug rules by the EC in 2000, there have been over 150 applications submitted. Fourteen products achieved orphan drug status in 2000 and many more companies followed suit in 2001 * * * .").[13]

Pharmaceutical innovation also lagged in the field of neonatal and pediatric medicine until Congress put in place patent-like incentives that expanded the scope of protectable subject matter. Drugs cannot be used on children merely because they have been FDA approved for adults. Dosages and responses are not linear; the metabolism and the absorption rates for the body of a child are different than those of an adult. Despite the urgent need for pediatric applications, the lack of profitability for that small market precluded development of new drugs. As a result, the majority of all drugs approved for adult populations had not been approved, or adequately tested, for pediatric populations. Christopher-Paul Milne, *Exploring the Frontiers of Law and Science: FDAMA's Pediatric Studies Incentive*, 57 Food & Drug L.J. 491, 491-94 (2002).

In response to these realities, Congress decided to provide patent-like incentives to previously unpatentable subject matter in the Food & Drug Administration Modernization Act of 1997

---

[13] "In the United States, the Bayh-Dole Act is credited with encouraging the creation of a whole generation of innovative startups from university research. It may be no coincidence that Japan's recent changes to its university system are designed to achieve precisely the same result." *Beyond Borders: Global Biotechnology Report 2005*, at 68 (Ernst & Young 2005).

("FDAMA"), Pub. L. No. 105-115, 111 Stat. 2296, 2305 (codified as amended at 21 U.S.C. § 355a (Supp. 1997)). FDAMA encourages pediatric testing by providing six months of market exclusivity for innovator drug sponsors who perform clinical studies on specific drugs for pediatric patients. *See* 21 U.S.C. § 355a(a) (2000).

The expansion of protectable subject matter succeeded. Prior to the enactment of the patent-like pediatric exclusivity provisions, only eleven of the seventy-one pediatric studies requested by the FDA were completed. *The Pediatric Exclusivity Provision: U.S. Food & Drug Admin. Jan. 2001 Status Report to Congress* at 8 (2001).[14] Over a six-year period between 1991 and 1996, drug sponsors agreed to complete seventy-one post-marketing pediatric studies, but then only eleven were actually completed. *Id.* All this changed with incentives.

The FDA reports that the "pediatric exclusivity provision has been highly effective for many drugs. In general, the industry's response has been vigorous and the public health benefits have been extensive." *Id.* Statistics from the FDA's website show that the patent-like incentives have significantly increased the number of drugs tested on pediatric patients. The FDA reports that drug sponsors had submitted 715 proposed study requests and the FDA had issued 311 written requests for studies as of December 2005. U.S. Food & Drug Admin. Ctr. for Drug Evaluation &

---

[14] *Available at* http://www.fda.gov/cder/pediatric/reportcong01.pdf.

Research, *Pediatric Drug Development*, http://www.fda.gov/cder/pediatric/ (last visited Jan. 31, 2006). Additionally, 115 grants of pediatric market exclusivity had been obtained as of December 2005. *Id.*

Thus, recent history shows that changes to patent-related laws expanding the scope of subject matter eligible for patent protection and patent-like exclusivity have resulted in economic growth and a pouring forth of significant innovations.

III. THIS CASE IS THE APPROPRIATE VEHICLE FOR BUILDING ON *CHAKRABARTY* AND *DIEHR*.

The distinction between patentable subject matter, on the one hand, and a law of nature, on the other hand, has never shimmered with lucidity.[15] Consequently, the prohibition is difficult to apply, and such application leads to arbitrary and artificial line drawing and patent claim drafting gamesmanship. This Court should use the present case to build on *Chakrabarty* and *Diehr* by discarding the arbitrary and unworkable prohibition.

---

[15] For example, electro-magnetic signals, when properly claimed, are patentable subject matter. *See Manual of Patent Examining Procedure* § 2106(B)(1)(c) (8th ed., Rev. Aug. 2005) ("However, a signal claim directed to a practical application of electromagnetic energy is statutory regardless of its transitory nature. *See O'Reilly*, 56 U.S. at 114-19; *In re Breslow*, 616 F.2d 516, 519-21, 205 USPQ 221, 225-26 (CCPA 1980)").

A. The Prohibition is Arbitrary and Has Always Been Difficult to Apply.

There is no bright line separating a patentable process from an unpatentable principle. Both are "[conceptions] of the mind, seen only by [their] effects when being executed or performed. Either may be the means of producing a useful result." *Tilghman* v. *Proctor*, 102 U.S. 707, 728 (1881); *see also Diehr*, 450 U.S. at 189 ("To accept the analysis proffered by the petitioner would, if carried to its extreme, make all inventions unpatentable because all inventions can be reduced to underlying principles of nature * * * ."); *Le Roy I*, 55 U.S. at 174 ("The word principle is used * * * with such want of precision in its application, as to mislead.").

This Court early on encountered the elusive distinction between a patentable new method and unpatentable known principles in two cases involving similar technology. *Dolbear* v. *Bell*, 126 U.S. 1 (1888), concerned only the scope of claims of the Bell patent of March 7, 1876:

> 5. The method of, and apparatus for, transmitting vocal or other sounds telegraphically, as herein described, by causing electrical undulations * * * .

Id. at 13-14. Yet, thirty-four years earlier, in *Morse*, 56 U.S. at 62, this Court seemed to have little trouble finding unpatentable subject matter in a similar claim in an application to Morse:

> [8.] * * * [T]he use of the motive power of electric or galvanic current * * * for making or

> printing intelligible characters, signs, or letters, at any distances * * * .

Id. at 107.

The distinction that made the *Bell* decision difficult, and the *Morse* decision less so, was not in any distinction between the similar subject matters, nor in the choice of claim language, but rather the scientific context. Galvanic current had been stored and discharged as early as 1790.[16] Experiments showed that such current could be transmitted by wire and that it could be used for communication. By 1819 or 1820, Hans Christian Oersted, a Danish philosopher, had discovered that a magnetic needle at a distance could be deflected by a galvanic current, and thus mark information.[17] In 1820, André Marie Ampère expressly stated that such a deflective needle could be used for telegraphing. *Smith* v. *Downing*, 22 F. Cas. 511, 512-13 (C.C.D. Mass. 1850). Indeed, "very soon after the discovery made by Oersted, it was believed by men of science that this newly-discovered power might be used to communicate intelligence to distant places." *Morse*, 56 U.S. at 94. Thus, this Court, in effect, resolved the *Bell*

---

[16] In 1746, the Abbé Jean Antoine Nollet, who became professor of experimental physics at Navarre, "used wire made of iron to connect a row of Carthusian monks more than a kilometre long"; when he discharged a Leyden jar through the wire, "the white-robed monks reportedly leapt simultaneously into the air." *See Biological Sciences*, 14 Encyclopedia Britannica 1069, 1096 (15th ed. 2005); *Electricity and Magnetism*, 18 Encyclopedia Britannica 159, 189 (15th ed. 2005).

[17] Gilbert Shapiro, *A Skeleton in the Darkroom: Stories of Serendipity in Science*, pp. 37-38 (HarperCollins 1986).

and the *Morse* decisions not on the basis of claiming or not claiming a law of nature, but rather on the basis that what Bell claimed was novel, and that what Morse claimed was obvious. As explained by Justice Grier in dissent, as a practical matter, dodging a decision based on whether what was claimed was a law of nature was unavoidable; attempting to draw a distinction based on subject matter is often impossible and usually unnecessary.[18]

This court again struggled with the elusive distinction between a patentable process and an unpatentable principle in *Tilghman*, 102 U.S. at 707. The sole claim of Tilghman's patent was directed to "the manufacturing of fat acids and glycerin from fatty bodies by the action of water at a high temperature and pressure." *Id.* at 709 (quoting U.S. Pat. No. 11,766 (Oct. 3, 1854)). The issue salient there was whether Tilghman was entitled to a claim on his process generally (viewed from a high degree of abstraction), or whether he was entitled to only a subset process limited by "the particular device mentioned" in the patent specification. *Id.* at 718. That claimed process might have included limitations on the time, temperature, and pressure of each step, the

---

[18] Justice Grier reviewed the stated policy rationales for prohibiting time-limited patent claims to laws of nature, and found those rationales lacking. He expressed concern that the line between patentable processes as opposed to unpatentable laws of nature was difficult to discern, and was better viewed as a prohibition on that which was known. In his view, the laws of England and the United States, in effect, permitted claims to laws of nature in general and would have allowed Morse's claim in particular. *Id.* at 130-35.

arrangement of tubing, and the composition of the reaction vessel, because all such parameters were nicely described in the specification. *Id.* at 721; *see also* U.S. Pat. No. 11,766 at page 2, 1st col. (issued Oct. 3, 1854). The more structural limitations and process parameters in the claim, the more the claim looks like a patentable process; the fewer structural limitations and process parameters, the more the claim looks like an unpatentable law of nature.

But again, the distinction was found not in the choice of claim language, but rather primarily the scientific context. Michel Eugène Chevreul[19] as early as 1813 had published his discovery of the law of nature that tallow consisted of a base of glycerin and fatty acids, specifically, stearic, margaric, and oleic acids. Chevreul in 1825 also patented a particular process using sulfuric acid to separate the glycerin from the fatty acids. *Id.* at 711. That process did not require preventing water under pressure from becoming steam. Analogously, this Court held that Tilghman too had discovered a law of nature, that the elements of neutral fats can be separated from each other by water. But this Court also held, while asserting that the line was difficult to draw, that Tilghman was entitled to claim as a process the practical application of performing that separation by "the action of water at a high temperature and pressure." *Id.* at 718, 730.

---

[19] Chevreul also invented the red, orange, yellow, green, purple, blue-color wheel. M. E. Chevreul, *De la Loi du Contraste Simultané des Couleurs et de l'assortiment des Object Colorés* (Paris 1839).

Without knowing the backdrop of the developments from 1813 to 1853, it is unlikely that Tilghman's process could have been seen to be a process rather than a law of nature. Patentability should not be based on serendipity.

The line between a law of nature and patentable subject matter shimmers with no greater clarity today. "Paroxetine hemihydrate is not the first invention to blur the line between [the workings of a] natural process and [its result,] a synthetic product * * * ." *SmithKline Beecham Corp.* v. *Apotex Corp.*, 403 F.3d 1331, 1360 (Fed. Cir. 2005) (Gajarsa, J., concurring); *see also Pres. & Fellows of Harvard Coll.* v. *Can. (Comm'r of Patents)*, [2000] 4 F.C. 528 (struggling "to distinguish between human intervention and the laws of nature," and dismissing appeal from decision of Comm'r of Patents denying an application for a transgenic mouse) (nonpatentability was affirmed by the Supreme Ct. of Can. at *Pres. & Fellows of Harvard Coll.* v. *Can. (Comm'r of Patents)*, [2002] 4 S.C.R. 45). Yet, the Harvard mouse is patentable subject matter under U.S. law. *See* United States Patent No. 4,736,866 to Leder, Philip, and Stuart, Timothy A., for "Transgenic Non-Human Mammals" issued April 12, 1988 assigned to President & Fellows of Harvard College, Cambridge, Mass.

This arbitrary, error-prone, and unworkable prohibition should be discarded.

B. This Court and Congress Consistently Have Moved Away from Arbitrary Line Drawing Regarding Patentable Subject Matter.

Prior to *Diehr*, the line with respect to the patentability of proto-software inventions was drawn by whether the patent claim included a mathematical algorithm. If it did, then it did not claim patentable subject matter. *Gottschalk*, 409 U.S. at 71-72 ("The mathematical formula involved here has no substantial practical application except in connection with a digital computer [so] the patent would wholly pre-empt the mathematical formula and in practical effect would be a patent on the algorithm itself."). This Court in *Diehr* erased that arbitrarily drawn line. 450 U.S. at 187 ("a claim * * * does not become nonstatutory simply because it uses a mathematical formula").

Likewise, in *Chakrabarty*, 447 U.S. at 303, this Court rejected drawing a line at "living inventions" even though some argued that that line had been clearly drawn by *Funk Bros. Seed Co.*, 333 U.S. at 131 (denying patentability to man-made mixture of six isolated bacterium recombined in respective quantities so as to be noninhibitive of each other) and *Am. Fruit Growers, Inc.* v. *Brogdex Co.*, 283 U.S. 1, 12 (1931) (denying patentability to man-made fungus-resistant citrus because: "It remains a fresh orange, fit only for the same beneficial uses as theretofore.").

Congress also eliminated certain arbitrary lines in the 1952 recodification of the Patent Law.

Risdon Iron & Locomotive Works v. *Medart*, 158 U.S. 68 (1895), had come to stand for a prohibition on claims directed to functions of a machine. This Court there held unpatentable a process for manufacturing belt pulleys, holding that no patent could "be obtained for a process which involves nothing more than the operation of a piece of mechanism, or, in other words, for the function of a machine." *Id.* at 77. Congress effectively erased that arbitrary distinction in the 1952 Patent Act by the broad inclusive language of § 101. *See In re Tarczy-Hornoch*, 397 F.2d 856, 867 (C.C.P.A. 1968) (Rich, J.) ("Exceptional treatment for this narrow class of processes is, pro tanto, inconsistent with the broad goal of the patent system * * * .").[20]

It was once believed that patentable weight could be given to printed materials only when a novel relationship was established between that printed material and the remaining structure of the claimed device or process. *See In re Miller*, 418 F.2d 1392, 1395 (C.C.P.A. 1969) (drawing line between patentable and nonpatentable subject matter). The Federal Circuit has since held that there is no support in 35 U.S.C. § 101 of the 1952 Patent Act for any such prohibition. *In re Gulack*, 703 F.2d 1381, 1384 (Fed. Cir. 1983) ("we do not interpret the board as holding that the printed matter can be ignored because it, by itself, is non-statutory subject matter"; if there is a basis for a

---

[20] Decisions of the Court of Customs and Patent Appeals are binding as precedent on the United States Court of Appeals for the Federal Circuit. *South Corp.* v. *U.S.*, 690 F. 2d 1368, 1371 (Fed. Cir. 1982).

"printed matter" rejection, it is obviousness under § 103).

Most recently, the courts have recognized that Congress intended by § 101 that no arbitrary line may be drawn to prohibit claims to methods of doing business. In the seminal decision, Judge Rich quoted the rationale from a dissent by Judge Newman in *In re Schrader*, 22 F.3d 290, 298 (Fed. Cir. 1994):

> '[The business method exception] is * * * an unwarranted encumbrance to the definition of statutory subject matter in section 101, that [should] be discarded as error-prone, redundant, and obsolete. It merits retirement from the glossary of section 101. * * * All of the 'doing business' cases could have been decided using the clearer concepts of Title 35 [meaning §§ 102, 103, and 112].'

State St. Bank & Trust Co., 149 F.3d at 1375.

Because the arbitrary prohibition against patent claims directed to so-called laws of nature was borne of dicta, is contrary to the expansive language of § 101, and likewise is error-prone, redundant, and obsolete, it should be discarded.

CONCLUSION

For the reasons presented above, this Court should either affirm without reaching the issue of patentable subject matter, or, in the alternative, hold the arbitrary prohibition against the patentability of so-called laws of nature overruled.

Respectfully submitted,

CRAIG STEVEN JEPSON
Professor of Law
Counsel of Record

FRANKLIN PIERCE
LAW CENTER
2 White Street
Concord, NH 03301
(603) 228-1541

Amicus Curiae